

PATENT APPLICATION TRANSMITTAL LETTER

Docket Number (Optional)

To the Commissioner of Patents and Trademarks:

Transmitted herewith for filing under 35 U.S.C. 111 and 37 CFR 1.53 is the patent application of

E. Alan Bates, Jeffrey Kovalik, Gary Hoffman

entitled An assaying device consisting of the test cartridge or cassette with a cap or cover which attaches onto the cartridge or cassette to cover and seal the well or opening into which the sample has been deposited

Enclosed are:

- ☒ 7 pages of written description, claims and abstract.
- ☒ 4 sheets of drawings.
- ☒ an assignment of the invention to DTx, Inc.
- ☒ executed declaration of the inventors.
- ☐ a certified copy of a _____ application.
- ☐ associate power of attorney.
- ☒ a verified statement to establish small entity status under 37 CFR 1.9 and 1.27.
- ☐ information disclosure statement
- ☐ preliminary amendment
- ☒ other: Copy of Disclosure Doc. #420500

CLAIMS AS FILED

	NUMBER FILED	NUMBER EXTRA	RATE	FEE
BASIC FEE			\$730	\$730
TOTAL CLAIMS	23 - 20 =	* 3	x \$22	66
INDEPENDENT CLAIMS	- 3 =	*	x \$76	
MULTIPLE DEPENDENT CLAIM PRESENT			\$240	
* NUMBER EXTRA MUST BE ZERO OR LARGER			TOTAL	\$ 796
If applicant has small entity status under 37 CFR 1.9 and 1.27, then divide total fee by 2, and enter amount here.			SMALL ENTITY TOTAL	\$ 398

- ☒ A check in the amount of \$ 398 to cover the filing fee is enclosed.
- ☐ The Commissioner is hereby authorized to charge and credit Deposit Account No. _____ as described below. I have enclosed a duplicate copy of this sheet.
 - ☐ Charge the amount of \$ _____ as filing fee.
 - ☐ Credit any overpayment.
 - ☐ Charge any additional filing fees required under 37 CFR 1.16 and 1.17.
 - ☐ Charge the issue fee set in 37 CFR 1.18 at the mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).

9-22-97

Date

Gary Hoffman
Signature

Gary Hoffman

Typed or printed name

285 Hawthorne Road

Pittsburgh PA 15209-1935

JCS14 U.S. PTO
09/23/97

A

DTxTM, Inc.
P.O. Box 101299
Pittsburgh PA 15237

September 23, 1997

Commissioner of Patents
and Trademarks
Washington D.C. 20231

Dear Sir:

Enclosed are the following items:

1. Patent Application Transmittal Letter
2. Seven pages of written description, claims and abstract
3. Four sheets of drawings
4. Assignment of invention to DTx, Inc.
5. Declaration for Patent Application
6. Verified Statement claiming small entity status
7. Check in the amount of \$398 filing fee
8. Check in the amount of \$40 for recording of the Assignment

This patent application is related to Disclosure Document No. 420500 a copy of which is enclosed.

Sincerely,


Gary Hoffman

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AN ASSAYING DEVICE CONSISTING OF THE TEST CARTRIDGE OR CASSETTE WITH A CAP OR COVER WHICH ATTACHES ONTO THE CARTRIDGE OR CASSETTE TO COVER AND SEAL THE WELL OR OPENING INTO WHICH THE SAMPLE HAS BEEN DEPOSITED

BACKGROUND

This invention generally relates to assaying devices and in particular the on-site immunoassay technology used to detect the presence of drugs in urine. On-site drug tests generally use an immunoassay method called antigen-antibody competitive binding to screen for the presence of drugs. Among the test kits used for such testing there are tests composed of a housing or container which contains a reagent test strip, an opening in which test results are displayed and a place for deposit of the sample. The sample wicks up into the reagent test strip and the results are displayed. The results are generally available within a few minutes. Often it is desirable to make a photocopy of the results, whether positive or negative, for a permanent record, since test results will change or disappear over time.

Possible problems include spilling of the sample, contamination of the sample, and contact by the test administrator or others with the sample during handling. A method is needed for a cleaner, more sanitary and easier handling of the test housing during and after the test administration, especially since specimens can be infectious. In order to photocopy the results, the test device is placed face down on the copier, so it is desirable to insure that sample will not leak onto the copier. Also a method is needed to insure a second sample from another donor is not inadvertently placed in the same test cartridge/cassette.

SUMMARY OF THE INVENTION

The housing or cartridge/cassette of the present invention will have one or two openings or "windows" in which the test results are displayed and one or two wells or openings in the top of the cartridge/cassette for deposit of the sample. The sample is placed in the

well/opening by use of a pipette. The results will be displayed in the window. The cartridge/cassette and the cap or cover of the present invention will prevent the sample used in the test from spilling out, will prevent contamination of the sample, and will permit cleaner, more sanitary and easier handling of the cartridge/cassette during and after the wicking test process. The cap/cover when placed on the cartridge/cassette will provide a fluid tight relationship. The cartridge/cassette with the cap/cover provide a compact, easy to handle unit. The cap/cover if placed on the cartridge/cassette as soon as the sample begins wicking will prevent inadvertent commingling or intermixing of another sample.

It is the principal object of this invention to provide a convenient, compact, easily managed device for the containment of the sample.

It is also a further objective to provide a means to protect the sample from contamination once placed into the test well/opening.

It is a further objective to provide a means to protect the test administrator from undesirable contact with the sample while handling the test cartridge during the test administration.

It is a further objective to provide a means to protect the test administrator or others from undesirable contact with the sample during subsequent handling of the test cartridge.

It is a further objective of the present invention to provide a means of insuring that while photocopying the test results displayed in the test cartridge/cassette the sample will not leak from the well/opening onto the copier.

It is a further objective of the present invention to provide a means to prevent the test administrator from inadvertently commingling or intermixing a second sample from another donor.

These and other objects of the present invention will become readily apparent upon further review of the following specifications and drawings.

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BRIEF DESCRIPTION OF THE DRAWING

In the Drawing:

Figure 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top;

Figure 2 is a perspective view of the cartridge/cassette and cap/cover snapped or slipped together as seen from the front;

Figure 3 is a perspective view of the cartridge/cassette with two windows and two sample well/openings and the cap/cover separately as seen from the front or top.

Figure 4 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of edges on the cartridge/cassette and indentations on the cap/cover for further securing the cap/cover.

Figure 5 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of indentations on the cartridge/cassette and raised buttons on the cap/cover for further securing the cap/cover.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top. The cartridge/cassette 1 contains an opening or window 2 in which the results on the test strip 3 will be displayed. The sample will be dropped into the well/opening 4 by means of a pipette. The cap/cover 5 has not been placed onto the cartridge/cassette yet.

Fig. 2 is a perspective view showing the cartridge/cassette and cap/cover snapped or slipped together. Fig. 2 is a view as seen from the front or top. The cartridge/cassette 1 with the results window 2 has the cap/cover 5 snapped or slipped into place. The sample well/opening, 4 in the other Figures, is now covered and sealed by the cap/cover 5 in a fluid tight relationship.

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Fig. 3 shows a cartridge/cassette 1 with two results windows 2, two test strips 3, two sample well/openings with a connecting channel 4 and a separate cap/cover 5. This type of cartridge/cassette will accommodate more separate tests and requires a greater quantity of the sample.

Fig. 4 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with a raised edge 6 and the cap/cover (shown in cross section) with indentations 7 which when snapped together will further insure the attachment.

Fig. 5 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with an indentation 6 and the cap/cover (shown in cross section) with a raised button 7 which when snapped together will further insure the attachment. The end of the cartridge/cassette where the well/opening is located has been reduced in thickness with the result that when the cap/cover is attached it will be flush with the edges of the cassette/cover.

What is claimed is new and to be protected as set forth in the appended claims. Obviously although the embodiments described herein are the preferred one, modifications can be made to the shape of the cartridge/cassette and the cap/cover, without departing from the spirit and scope of this invention. The cartridge/cassette and the cap/cover may be formed or molded from any suitable material, usually plastic or other similar material, but the invention should work as well with most drug test materials. The cap is effective if it slips onto the cartridge/cassette snugly enough to insure that it will cover and seal the top of the sample well in a fluid tight relationship and will not detach. Raised buttons or edges can also be incorporated into the design of the cartridge/cassette and cap/cover to further insure that the cap/cover when snapped or slipped into place will not detach from the cartridge/cassette. The number of windows and urine well/openings shown are currently available, but more will not depart from the spirit and scope of this invention.

CLAIMS

What is claimed are:

1. An assaying device for depositing and analyzing a sample, comprising of: a cartridge/cassette means which contains the test strip, a window for viewing the test results and a well/opening for deposit of the sample; and a cap/cover means for sealing the top of the sample well in a fluid tight relationship.
2. An assaying device according to claim 1, which when attached together, further comprising means for containment of the sample used in the test.
3. An assaying device according to claim 1, which when attached together, further comprising means for protection of the sample from contamination during the test.
4. An assaying device according to claim 1, which when attached together, further comprising means for protection of the test administrator against contact with the sample during the test administration.
5. An assaying device according to claim 1, which when attached together, further comprising means for protection of the test administrator and others processing the test cartridge against contact with the sample during subsequent handling of the cartridge.
6. An assaying device according to claim 1, which when attached together, further comprising means for containment of the sample during photocopying of the test results.
7. An assaying device according to claim 1, which when attached together, further comprising means for insuring that a second sample from another donor is not placed into the well/opening.
8. A drug screening device for depositing and analyzing a urine sample, comprising of: a cartridge/cassette means which contains the drug test strip, a window for viewing the results and a well/opening for deposit of the urine sample, and a cap/cover means for sealing the top of the sample well in a fluid tight relationship.

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9. A drug screening device according to claim 8, which when attached together, further comprising means for containment of the urine sample used in the drug test.
10. A drug screening device according to claim 8, which when attached together, further comprising means for protection of the urine sample from contamination during the drug test.
11. A drug screening device according to claim 8, which when attached together, further comprising means for protection of the test administrator against contact with the urine sample during the drug test administration.
12. A drug screening device according to claim 8, which when attached together, further comprising means for protection of the test administrator and others processing the drug test cartridge against contact with the urine sample during subsequent handling of the cartridge.
13. A drug screening device according to claim 8, which when attached together, further comprising means for containment of the urine sample during photocopying of the drug test results.
14. A drug screening device according to claim 8, which when attached together, further comprising means for insuring that a second urine sample from another donor is not placed into the well/opening.
15. A cap/cover article which when attached onto a test cartridge/cassette containing a reagent test strip, window for viewing the test results and a well/opening in the top of the cartridge/cassette for deposit of the test sample, covers and seals the top of sample well in a fluid tight relationship.
16. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for containment of the sample used in the test.
17. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for protection of the sample from contamination during the test.

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18. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for protection of the test administrator against contact with the sample during the test administration.
19. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for protection of the test administrator and others processing the test cartridge against contact with the sample during subsequent handling of the cartridge/cassette.
20. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for containment of the sample during photocopying of the test results.
21. A cap/cover article according to claim 15 which when attached onto a test cartridge/cassette further comprising means for insuring that a second sample from another donor is not placed into the well/opening.
22. An assaying device according to claim 1, whereby the top of the sample well is secured in a fluid tight relationship.
23. A method of securing the top of the sample well of an assaying test device in a fluid tight relationship, comprising the steps of: depositing the test sample into the sample well of the cartridge/cassette; attaching the cap/cover to cover and seal the top of the sample well.

ABSTRACT OF THE DISCLOSURE

An assaying device composed of a test cartridge/cassette and cap/cover which when attached together provide protection from contact with and contamination of the tested sample, provide for easier, cleaner handling of the test cartridge/cassette and prevent intermixing of another sample.

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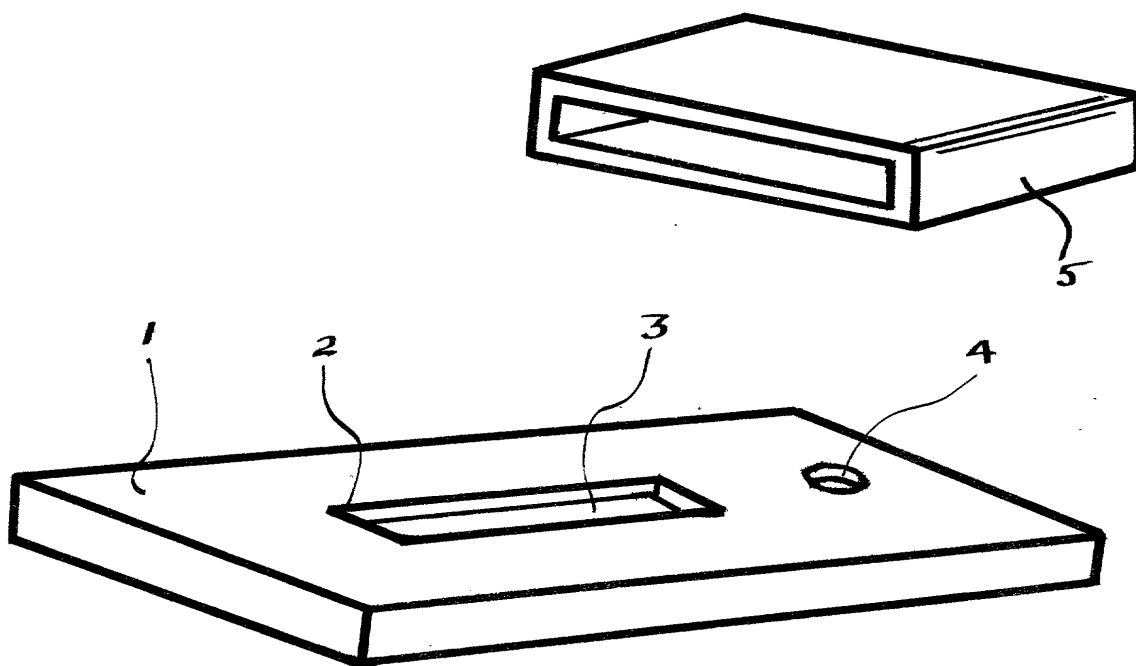


FIG. 1

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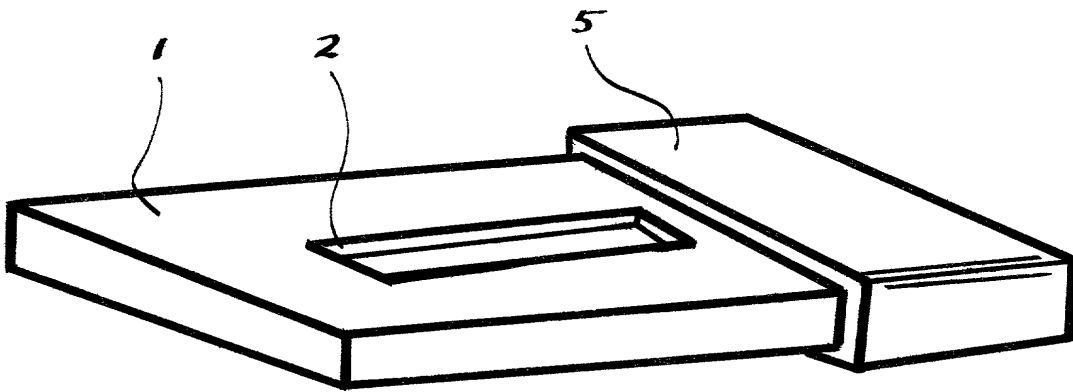


FIG. 2

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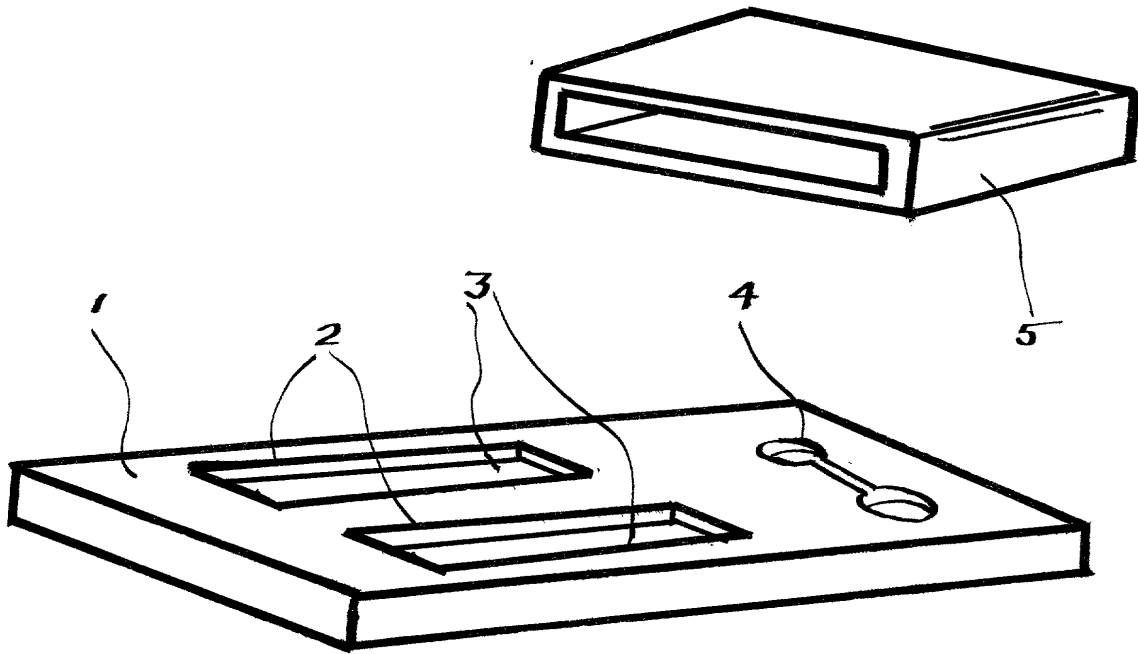


FIG. 3

FIG. 4

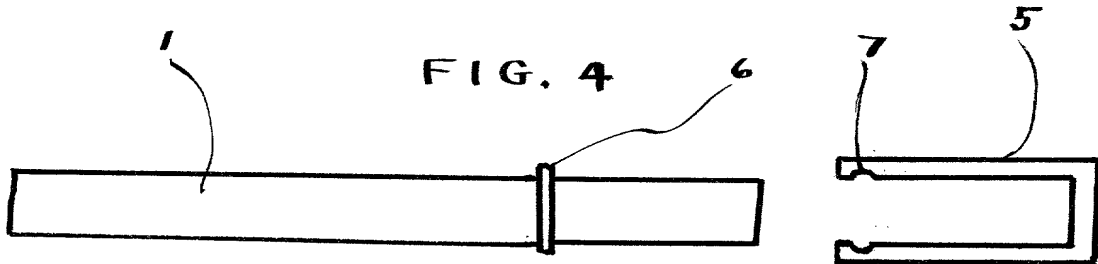
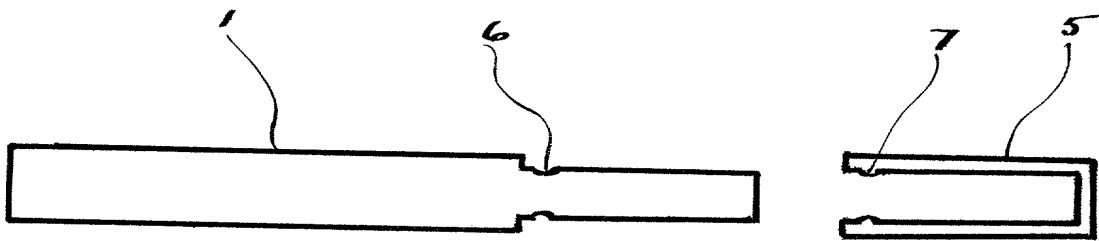


FIG. 5



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DECLARATION FOR PATENT APPLICATION

Docket Number (Optional)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled An assaying device consisting of the test cartridge or cassette with the specification of which a cap or cover which attaches onto the cartridge or cassette to cover and seal the well is attached hereto unless the following box is checked: or opening into which the sample has been deposited
☐ was filed on _____ as United States Application Number or PCT International Application Number _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

☐ Yes ☐ No

(Number) _____ (Country) _____ (Day/Month/Year Filed) _____

☐ Yes ☐ No

(Number) _____ (Country) _____ (Day/Month/Year Filed) _____

☐ Yes ☐ No

(Number) _____ (Country) _____ (Day/Month/Year Filed) _____

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Number) _____ (Filing Date) _____ (Status - patented, pending, abandoned) _____

(Application Number) _____ (Filing Date) _____ (Status - patented, pending, abandoned) _____

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Address all telephone calls to Gary Hoffman at telephone number (412) 821-2420
Address all correspondence to Gary Hoffman
285 Hawthorne Road
Pittsburgh PA 15209-1935

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name) E. Alan Bates
Inventor's signature [Signature] Date 9-22-97
Residence 9803 Braewick Dr., Allison Park, PA Citizenship U.S.A.
Post Office Address 803 McKnight Park Drive, Pittsburgh PA 15237

Full name of second joint inventor, if any (given name, family name) Jeffrey Kovalik
Second Inventor's signature [Signature] Date 9-22-97
Residence 2535 Sylvania Dr. Bethel Park PA Citizenship U.S.A.
Post Office Address 476 Route 51, Large PA 15025

☒ Additional inventors are being named on separately numbered sheets attached hereto.

additional Sheet 1 of 1
Declaration for Patent Application

Full name of third joint inventor
Third inventor's signature

Date

Residence

Post Office Address

Citizenship

Gary Hoffman



9-22-97

285 Hawthorne Road
Pittsburgh PA 15209-1935

same

U.S.A.

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Applicant or Patentee: E. Alan Bates, Jeffrey Kovalik, Gary Hoffman Attorney's
 Serial or Patent No.: _____ Docket No.: _____
 Filed or Issued: _____
 For: An assaying device consisting of the test cartridge or cassette with a cap or
cover which attaches onto the cartridge or cassette to cover and seal the well or opening
into which the sample has been deposited

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
 STATUS (37 CFR 1.9 (f) and 1.27 (b)) — INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9 (c) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled An assaying device consisting of the test cartridge or
cassette with a cap or cover which attaches onto the cartridge or cassette
to cover and seal the well or opening into which the sample has been deposited

☒ the specification filed herewith
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9 (c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☐ no such person, concern, or organization
☒ persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

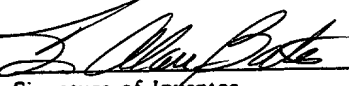
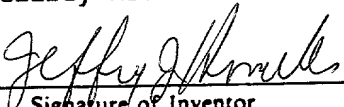
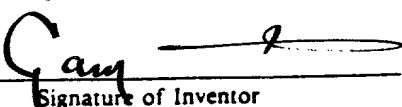
FULL NAME DTx, Inc.
 ADDRESS 285 Hawthorne Road Pittsburgh PA 15209-1935
☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

<u>E. Alan Bates</u>	<u>Jeffrey Kovalik</u>	<u>Gary Hoffman</u>
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
<u>E. Alan Bates</u>	<u>Jeffrey Kovalik</u>	<u>Gary Hoffman</u>
		
Signature of Inventor	Signature of Inventor	Signature of Inventor
<u>9-22-97</u>	<u>9-22-97</u>	<u>9-22-97</u>
Date	Date	Date